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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/812,291	03/20/2001	Mahesh Tangellapally	01-101	2280
23843	7590	11/02/2005	EXAMINER	
FOOTHILL LAW GROUP, LLP			GOTTSCALK, MARTIN A	
3333 BOWERS AVE., SUITE 130			ART UNIT	
SANTA CLARA, CA 95054			PAPER NUMBER	

3626

DATE MAILED: 11/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)	
09/812,291	TANGELLAPALLY ET AL.	
Examiner	Art Unit	
Martin A. Gottschalk	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 19-31 is/are pending in the application.
- 4a) Of the above claim(s) 25-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 19-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 March 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>02/28/02</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice to Applicant

1. This Office Action is in response to the communication filed 08/03/2005. Claims 1-6, and 19-25 are pending. Claims 7-18 were cancelled per Applicant's communication filed 07/20/2005. New claims 25-31 are withdrawn as per the comments in the following section.

Election/Restrictions

2. Newly submitted claims 25-31, per Applicant's remarks on page 11 of the communication filed 08/03/2005, correspond to claims 11-14 and 16-18 which were not elected as per Applicant's remarks on page 6 of the communication filed 07/20/2005. Furthermore, claims 25-31 as written do not appear to depend from claim 1 as is asserted on page 11 of the communication filed 08/03/2005, but rather claims 25 and 29 are independent claims with the remaining dependent claims 26-28 and 30-31 depending from them respectively. Accordingly, claims 25-31 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1-6 and 19-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goetz et al (US Pat# 6,421,650, hereinafter Goetz) in view of Mayaud (US Pat# 5,845,255, hereinafter Mayaud).

A. As per claim 1, Goetz discloses a method for managing healthcare data which allows a healthcare user to assemble a virtual healthcare clinic, the method comprising the acts of:

a) providing a central data base system capable of holding health records

(Goetz: col 4, lns 17-21),

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wherein said data base is accessible through at least one public connection (Goetz: col 12, Ins 56-59);

b) enrolling a plurality of healthcare practitioners to create a plurality of enrolled healthcare practitioners (regarding the issue of plurality, the Examiner notes that the system of Goetz maintains a medical history of a patient, including the plurality of health care practitioners the patient uses, Goetz: col 2, Ins 22-27, and that the system, "Provides a vehicles for interchange <of> data among various individuals involved in patient care such as patient, physician, pharmacist, emergency medical personnel, and hospital personnel." The Examiner considers this to be a suggestion that the use of the system is to be by a plurality of healthcare practitioners, pharmacists, and patients).

wherein enrolling a healthcare practitioner comprises

providing the healthcare practitioner with software operable on a computer system (Goetz: col 9, Ins 45-49) for

reading information from medical portable access devices and writing treatment information including medical prescriptions, to said medical portable access devices (Goetz: col 9, Ins 45-65);

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c) enrolling a plurality of pharmacies to create a plurality of enrolled pharmacies
(see the rejection of step b),

wherein enrolling a pharmacy comprises

providing the pharmacy with software operable on a computer
system for reading healthcare information including medical
prescriptions written by one of the plurality of enrolled healthcare
practitioners from said medical portable access devices (Goetz: col
5, lns 57-67);

d) enrolling a patient member (Goetz: col 4, section entitled "Patient Component").

The Examiner considers providing the patient component to be a form of
enrolling a patient, just as enrolling healthcare practitioners in step b and
pharmacies in step c involved providing those parties with software possessing
pertinent functionality);

e) providing said patient member with a medical portable access device (Goetz:
col 5, lns 5-11);

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f) programming said medical portable access device provided to said member with healthcare information relevant to said patient member (Goetz: col 4, lns 50-65);

g) synchronizing the healthcare information on said medical portable access device with the healthcare information contained in said central data base (Goetz: col 3, lns 8-11; col 5, lns 50-51); and

h) repeating acts (d), (e), (f) and (g) for a plurality of patient members creating a plurality of enrolled patient members each having a medical portable access device (See the rejection of step b regarding the plurality issue.)

whereby by an enrolled patient member can create a virtual clinic of healthcare providers by choosing enrolled healthcare practitioners and enrolled pharmacies and presenting the portable access device provided to the member for updating at healthcare treatments and prescription fulfillment (With respect to the invention disclosed by Goetz, the Examiner considers that once a patient possesses a "patient component" device, the patient could choose to create the claimed virtual clinic, as this would be one among the many choices the patient would have for using the device. The Examiner notes the disclosure of presenting of the device to chosen providers and

pharmacists and the associated updating of treatment and prescription information, Goetz: col 5, Ins 35-62).

Goetz suggests but fails to explicitly disclose

c) providing the pharmacy with software operable on a computer system for reading healthcare information including medical prescriptions written by one of the plurality of enrolled healthcare practitioners from said medical portable access devices

for writing a confirmation that a prescription has been filled to said medical portable access devices (Goetz: col 11, Ins 29-51. Note that the pharmacist "...verifies the authenticity of the prescription..." and then fills the prescription. The Examiner considers the subsequent filling step to include a writing step which also serves as a written confirmation), and

transmitting an electronic message to the one of said plurality of enrolled healthcare practitioners who wrote the prescription (Goetz: col 12, Ins 1-21. The Examiner notes that the pharmacist can flag an interaction which is stored on the patient device, which can

subsequently be read by the physician when the patient consults with the physician);

However, these features are well known in the art as evidenced by the teachings of Mayaud.

Mayaud teaches a portable electronic prescription management system (Mayaud: col 7, Ins 57-67) enabling communications between a plurality of participants in the prescription process (Mayaud: col 7, Ins 12-29; Fig 16). This communication includes the ability of a pharmacy to provide electronic (Mayaud: col 36, Ins 16-22) notification (i.e. confirmation) to a prescribing physician regarding the fulfillment of a prescription (Mayaud: col 28, Ins 23-29).

It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate the teachings of Mayaud within the method of Goetz with the motivation of providing both the ability to monitor potential prescription abuse by a patient, and to enhance patient compliance with a prescribed treatment regimen (Mayaud: col 28, Ins 30-37).

B. As per claim 2 Goetz, discloses the method of claim 1 further comprising the act of

providing a plurality of patient members with software operable on a computer system for reading the contents of their medical portable access device (Goetz: col 7, lns 3-4; Fig 4), and

writing updated information on the medical portable access device (Goetz: Fig 7, note for example item labeled "SET THE TIME FOR THE NEXT DOSE FOR THE MISSED DOSE"; col 14, lns 17-19).

C. As per claim 3, Goetz discloses the method of claim 2 wherein

each medical personal access device is a smart card (Goetz: col 4, lns 17-24; Fig 1, item 14).

D. As per claim 4, Goetz discloses the method of claim 3 further comprising

providing enrolled healthcare practitioners, enrolled pharmacies, and enrolled patient members with software functionality for

optional connection to the central database system during use of a portable access device (Goetz: col 8, lns 59-62), and

wherein the central database is synchronized with the portable access device approximately contemporaneously with writing to the personal access device if the central database is optionally connected (Goetz: col 8, Ins 59-67).

E. As per claim 5 Goetz discloses the method of claim 4 further comprising providing software functionality to enrolled pharmacies which causes an enrolled pharmacy

to send an electronic confirmation to a healthcare provider (Goetz: col 13, Ins 1-6. The Examiner considers documenting and sending information to the medical community about interactions and side effects to be a form of confirmation in the sense that this confirms the presence or absence of same for an experimental drug in a trial situation.) and

to send an electronic confirmation to the central data base when the enrolled pharmacy fulfills a prescription prescribed by the health provider (Goetz: col 12, Ins 52-62. The Examiner considers the augmented information provided as part of the prescription fulfillment process to be a form of confirmation that the prescription

has been filled, i.e., the augmentation only happens if the prescription has been fulfilled.),

F. As per claim 6, Goetz discloses the method of claim 5 further comprising

providing software enrolled healthcare practitioners, enrolled pharmacies, and enrolled patient members with software functionality for

authenticating the identity of users (Goetz: col 2, lns 52-58, reads on “..PIN or password would be necessary...”; also col 11, lns 43-46).

G. As per claims 19-21, 23, and 24, they are system claims which repeat the same limitations of claims , the corresponding method claims, as a collection of elements as opposed to a series of process steps. Since the teachings of Goetz and Mayaud disclose the underlying process steps that constitute the methods of claims 1-6, it is respectfully submitted that they provide the underlying structural elements that perform the steps as well. As such, the limitations of claims 19-21, 23, and 24 are rejected for the same reasons given above for claims 1-6.

H. As per claim 22 Goetz fails to disclose the healthcare information system of claim 21 wherein said healthcare provider computer systems, said pharmacy computer systems, and said patient computer systems further comprise

a biometric measurement device for authenticating users.

However, these features are well known in the art as evidenced by the teachings of Mayaud (Mayaud: col 9, lns 16-27; col 10, lns 4-10).

It would have been obvious at the time of the invention for one of ordinary skill in the art to combine the teachings of Mayaud into the system of Goetz with the motivation of permitting remote electronic authorization of prescription fulfillment, particularly at a mail order pharmacy (Mayaud: col 9, lns 36-39).

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited but not applied prior art discloses complete systems for managing healthcare-related information (US 5,301,105; US 6,283,761), and prescriptions (US 4,847,764; US 6,493,427), and health care systems employing smart cards (US 5,659,741), and biometric technology for identification verification (US 6,539,101).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Martin A. Gottschalk whose telephone number is (571) 272-7030. The examiner can normally be reached on Mon - Fri 8:30 - 5.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571) 272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



MG
10/19/2005



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